WHO COLLABORATIVE REGISTRATION FROM REGULATOR’S POINT OF VIEW

UN CITY, COPENHAGEN
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Outline

• Introduction
• Review of CRP applications
• Products registered under CRP
• NMRA experience
• Conclusion
• Future prospects
Introduction

• Tanzania Food and Drugs Authority (TFDA) is a Statutory organization under the Ministry of Health, Community Development, Gender, Elderly and Children

• Established under sect. 4 of the Food, Drugs and Cosmetics Act, Cap 219

• **Mission**: Protection and promotion of public health by ensuring quality, safety and effectiveness of medicines, food, cosmetics and medical devices

• **Vision**: To be the leading African regulatory Authority in ensuring safe, quality and effective food, medicines, cosmetics and medical devices for all.
Location Map of Tanzania
Medicine Registration in Tanzania

• Legal requirement:
  – Quality, Safety, Efficacy…GMP compliance (site)

• CTD implemented in July 2015 (EAC Harmonized CTD)

• Over 4000 brands registered (90% human meds and 10% veterinary meds)

• Two streams and timelines:
  – Regular track: 240 days
  – Fast track: 120 days
Registered so far?

![Graph showing the percentage of medicine categories registered so far.](image)
Review of applications

• Submission by the applicant (dossier same as PQ’d);
  - Dossier (Module 1 – 5): Including Country specific information
  - Application fees
  - Product samples
  - GMP application

• Data entry and priority in assessment (along with other fast track applications)

• Assigned to Quality and Clinical assessors
Information shared in MedNet → Clock starts
Review....

- **Abridged review:**
  - Module 1 (GMP? Labelling)
  - Sites (API, FPP, CRO?)
  - Formulae (Unit and Batch): Quality standards?
  - Specifications (API, FPP)
  - CCS (Description & Specifications)
  - Stability (if Shelf life longer then PQ’d)

- **Comparison with PQ’d information (Assessment reports, QIS & related information)**

- **All in 90 days** (Including Manufacturer’s time)

- **Request for additional information (where necessary)**
Review…..

• Assessment of additional data…priority review

• Inspectorate …GMP status (FPP site)

• Technical Committee:
  - risk benefit
  - relevance
  - treatment guidelines
  - medicine policies etc

• Approval and communication: within 30 days
Review...

• Communication
  - WHO- Interactive forms: MedNet
  - Applicant/Registrant: Reg.Certificate (5 years validity)
  - Public: Website (http://www.tfda.go.tz/portal/registered-products/registered-drug-products-1)

• Post registration: NMRA and WHO share information;
  - variations
  - withdrawal
  - suspension
  - delisting from PQd list, or
  - national deregistration
CRP & Tanzania

- Agreed to participate in 2013
- 21 applications received
- 19 products registered
- 2 pending

Registration times:
- 0-90 days: 13 products
- 90-120 days: 4 products
- 120+ days: 2 products
<table>
<thead>
<tr>
<th>S/N</th>
<th>Product name</th>
<th>Registrant</th>
<th>Registration time (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Levonogestrel 750 mcg</td>
<td>DKT International</td>
<td>49</td>
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<tr>
<td>2</td>
<td>Levonogestrel 1.5 mg</td>
<td>DKT International</td>
<td>49</td>
</tr>
<tr>
<td>3</td>
<td>Levonogestrel/Ethinylestradiol 150 + 30 mcg</td>
<td>DKT International</td>
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<tr>
<td>4</td>
<td>Zinnia F 150mcg + 30mcg + 75mg</td>
<td>Jai Pharma Limited</td>
<td>18</td>
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<tr>
<td>5</td>
<td>Levonogestrel 1.5mg</td>
<td>Jai Pharma Limited</td>
<td>56</td>
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<tr>
<td>6</td>
<td>Levonogestrel 750mcg</td>
<td>Jai Pharma Limited</td>
<td>56</td>
</tr>
<tr>
<td>7</td>
<td>Levofloxacin 750 mg</td>
<td>Macleods Pharmaceuticals Limited</td>
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## Products

<table>
<thead>
<tr>
<th>S/N</th>
<th>Product name</th>
<th>Registrant</th>
<th>Registration time (days)</th>
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<tbody>
<tr>
<td>8</td>
<td>Ethionamide 250 mg</td>
<td>Macleods</td>
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<tr>
<td>9</td>
<td>Moxifloxacin 400 mg</td>
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<tr>
<td>10</td>
<td>Emtricitabine 200 mg+Tenofovir 300 mg</td>
<td>Hetero Laboratories</td>
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<tr>
<td>11</td>
<td>Tenofovir 300 mg+Efavirenz 600 mg+Emtricitabine 200 mg</td>
<td>Hetero Laboratories</td>
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<td>12</td>
<td>Efavirenz 600 mg+Emtricitabine 200+Tenofovir 300 mg</td>
<td>Macleods</td>
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</table>
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</thead>
<tbody>
<tr>
<td>13</td>
<td>Artemether 20 mg + Lumefantrine 120 mg</td>
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<td>24</td>
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<tr>
<td>14</td>
<td>Efavirenz 600 mg + Lamivudine 300 mg + Tenofovir 300 mg</td>
<td>Macleods</td>
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<tr>
<td>15</td>
<td>Artesunate 25 mg + Mefloquine 50 mg</td>
<td>Cipla Limited</td>
<td>90</td>
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<tr>
<td>16</td>
<td>Artesunate 100 mg + Mefloquine 200 mg</td>
<td>Cipla Limited</td>
<td>93</td>
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<tr>
<td>17</td>
<td>Lamivudine 300 mg + Tenofovir 300 mg</td>
<td>Cipla Limited</td>
<td>40</td>
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<tr>
<td>S/N</td>
<td>Product name</td>
<td>Registrant</td>
<td>Registration time</td>
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<tr>
<td>-----</td>
<td>-----------------------------------------------------------</td>
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</tr>
<tr>
<td>18</td>
<td>Lopinar 100 mg + Ritonavir 25 mg</td>
<td>Macleods</td>
<td>73</td>
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<tr>
<td>19</td>
<td>Nevirepine 200 mg tablets</td>
<td>Strides</td>
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<tr>
<td>20</td>
<td>Tenofovir disoproxil fumarate 300 mg</td>
<td>Pending 243</td>
<td>243</td>
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<tr>
<td>21</td>
<td>Pyrazinamide Dispersible Tablets 150mg</td>
<td>Pending 90</td>
<td></td>
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</tbody>
</table>

* Reviewed in 75 days, 188 days awaiting responses from manufacturer)
**Experience**

- **Significantly shortens the approval time:**
  - Early market access
  - Access to patients

- **Brings closer NMRAs with manufacturer:** Than ever before → Quick communication and resolution of the issues;

- **Builds capacity:** WHO PQ assessment and inspection reports;

- **Facilitates regulatory harmonization:** Work sharing and mutual recognition
Conclusion

• CRP → useful option, practically works!

• Commitment of regulators, manufacturers and collaborating partners (WHO)

• Active focal persons (regulators and manufacturer)

• Way to go: In scientific advancements, and pressure to regulators and manufacturers
Future?

- **Other product streams:** vaccines, diagnostics and medical devices?

- **Further fuel Harmonization Initiatives** → EAC MRH, SADC MRH:
  - Quick access to new big markets (150m & 227m)
  - Promote public health

Detailed information: [www.mrh.eac.int](http://www.mrh.eac.int)
Thank you very much